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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,563	10/31/2003	Najla Guthrie	182718-335142	8415

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DAVIDSON, DAVIDSON & KAPPEL, LLC
485 SEVENTH AVENUE, 14TH FLOOR
NEW YORK, NY 10018

EXAMINER

WEDDINGTON, KEVIN E

ART UNIT PAPER NUMBER

1614

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/697,563

Applicant(s)

GUTHRIE ET AL.

Examiner

Kevin E. Weddington

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 8-23 are presented for examination.

Applicants' information disclosure statement filed April 30, 2004 has been received and entered.

Applicants' election filed August 13, 2004 in response to the restriction requirement of July 16, 2004 has been received and entered. The applicants elected the invention described in claims 8-23 (Group II) without traverse. Note the applicants cancelled claims 1-7.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8-14 are rendered indefinite by the phrase "use of" which is not an acceptable claim language used in the U.S. Patent Office and is normally rejected under 35 USC 101, but since the Examiner understands the claims are "method of use", then the rejection is made under 35 USC 112, second paragraph.

Claims 8-14 are not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8, 13-15 and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bok et al. (6,096,364) of PTO-1449.

Bok et al. teach blood glucose level lowering bioflavonoids, also known as polymethoxyflavones. Note particularly column 5, lines 3-6 states the bioflavonoids can be administered via various routes including oral, transdermal, subcutaneous, intravenous and intramuscular (same as applicants' claims 13, 14, 20 and 21). Also note in column 5, lines 5-9, the bioflavonoids are administered to humans in a typical daily dosage range from about 0.1 to 500 mg/kg (note applicants' dosage ranges from up to 5000 mg/day or preferred dose of up to 70 mg/kg/day). Clearly, applicants' dosage range falls within the Bok et al. range. Since high levels of sugar (glucose) in the blood is one of the symptoms associated the metabolic syndrome, also called the syndrome of insulin resistance (see the enclosed THE MERCK MANUAL of MEDICAL INFORMATION, page 926), the administration of bioflavonoids, also known as polymethoxyflavones, would inherently treat insulin resistance syndrome. Clearly, the cited reference anticipates the applicants' instant invention; therefore, the instant invention is unpatentable.

Claims 8, 13-15 and 20-23 are not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-10, 13-17, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurowska et al., "Hypolipidemic activities of tangeretin, a flavonoid from tangerine in vitro and in vivo", Annual Meeting of the Federation of American Societies for Experimental Biology on Experimental Biology 2001, March 7 of PTO-1449.

Kurowska et al. teach tangeretin, a flavonoid or a polymethoxyflavone, possesses hypolipidemic activity. (See the abstract) Note tangeretin is administered orally to rabbits and hamsters. Since high cholesterol levels is another symptom associated with the metabolic syndrome, also called the syndrome of insulin resistance (see the enclosed THE MERCK MANUAL OF MEDICAL Information, page 926), the administration of tangeretin would inherently treat insulin resistance syndrome. Also note on page 926 of THE MERCK MANUAL, it states many people with metabolic syndrome need to take lipid-lowering drugs. Clearly, the cited reference anticipates the applicants' instant invention; therefore, the instant invention is unpatentable.

Claims 8-10, 13-17, 20 and 21 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11, 12, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bok et al. (6,096,364) in view of Kurowska et al., Annual Meeting of the Federation of American Societies for Experimental Biology on Experimental Biology 2001.

Bok et al. were discussed above supra for the use of blood glucose level lowering bioflavonoids to treat insulin resistance syndrome.

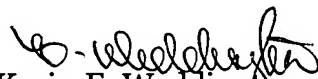
The instant invention differs from the cited reference in that the cited reference does not teach the addition of a second bioflavonoid also known as polymethoxyflavone. However, the secondary reference, Kurowska et al., teaches tangeretin, a well-known hypolipidemic agent used to treat insulin resistance syndrome. Clearly, one skilled in the art would have assumed the mere combination of two bioflavonoids (polymethoxyflavone) into a single composition would give an additive effect in the absence of evidence to the contrary.

Claims 11, 12, 18 and 19 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
February 22, 2005